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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,579	07/10/2003	Ellen Codd	PRD-0020-NP	1328

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EXAMINER

SEAMAN, D MARGARET M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,579

Applicant(s)

CODD ET AL.

Examiner

D. Margaret Seaman

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-120 is/are pending in the application.
- 4a) Of the above claim(s) 38-54,85-92,95-106,109-113 and 116-120 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-37,55-84,93,94,107,108,114 and 115 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-120 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application was filed 7/10/2003 and claims benefit of Provisional Application 60/395,728 (7/12/2002). Claims 1-120 are before the Examiner and are subject to the following restriction requirement.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-20, 38-54, 72, 73, 78-81, 83-84 and 100-101 (in part), drawn to compounds and compositions wherein $Y = C$ and $X = CH$, classified in class 562, subclass 27+.
 - II. Claim 1 (in part), drawn to compounds wherein $Y = N$ and $X = CH$, classified in class 546, subclass 153+.
 - III. Claim 1 (in part), drawn to compounds wherein $Y = N$ and $X = N$ or $N \rightarrow O$, classified in class 544, subclass 79+.
 - IV. Claims 1-37, 55-84, 93-94, 107, 108, 114 and 115 (in part), drawn to compounds wherein $Y = C$ and $X = N$ or $N \rightarrow O$, classified in class 546, subclass 139+.
 - V. Claims 85 (in part), drawn to a method of treating or preventing a disease that is modulated by one or more vanilloid receptors limited to compounds of formula I wherein $Y = C$ and $X = CH$, classified in class 514, class 400+.

- VI. Claims 85 (in part), drawn to a method of treating or preventing a disease that is modulated by one or more vanilloid receptors limited to compounds of formula I wherein $Y=C$ and $X=N$ or $N \rightarrow O$, classified in class 514, class 305+.
- VII. Claims 86 and 87 (in part), drawn to a method of treating or preventing chronic-pain causing disease, acute-pain causing disease or a pulmonary dysfunction wherein $Y=C$ and $X=CH$, classified in class 514, class 400+.
- VIII. Claims 86 and 87 (in part), drawn to a method of treating or preventing chronic-pain causing disease, acute-pain causing disease or a pulmonary dysfunction wherein $Y=C$ and $X=N$ or $N \rightarrow O$ classified in class 514, class 305+.
- IX. Claims 88-91 (in part) and claims 102-105, drawn to a method of treating or preventing diseases wherein $Y=C$ and $X=CH$, classified in class 514, class 400+, with an election of species of the condition being treated.
- X. Claims 88-91 (in part) and claims 95-98, 109-112 and 116-119, drawn to a method of treating or preventing diseases wherein $Y=C$ and $X=N$ or $N \rightarrow O$ classified in class 514, class 305+, with an election of species of the condition being treated.
- XI. Claim 92 (in part) and claim 106, drawn to a kit containing compounds of formula I wherein $Y=C$ and $X=CH$, classified in class 562, subclass 27+.

XII. Claim 92 (in part) and claims 99, 113 and 120, drawn to a kit containing compounds of formula I wherein $Y=C$ and $X=N$ or $N \rightarrow O$, classified in class 546, subclass 139+.

2. The inventions are distinct, each from the other because of the following reasons:

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Invention Set listed above (groups I-IV) is directed to or involves compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions, i.e. they are patentable over each other. Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior

art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The products of Groups I-IV differ materially in structure and element so much so as to be patentably distinct. In addition, a reference, which anticipates one group, may not even render obvious the other.

Inventions of Groups I-IV and Groups V-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product.

3. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for Group I, for example, is not required for Groups II-XII, restriction for examination purposes as indicated is proper. Therefore, it would impose an undue burden on the Examiner and the Patent Office's resources to examine the instant application if unrestricted.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re*

Brouwer and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

5. During a telephone conversation with Matthew Zisk on 3/9/2005 a provisional election was made with traverse to prosecute the invention of group IV, claims 1-37, 55-84, 93, 94, 107, 108, 114 and 115 (in part). Affirmation of this election must be made by applicant in replying to this Office action. Claims 38-54, 85-92, 95-106, 109-113 and 116-120 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

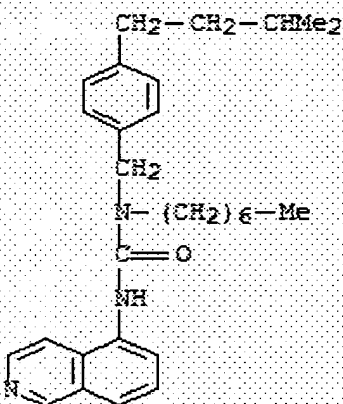
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-37, 55-84, 93, 94, 107, 108, 114 and 115 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 418071. EP teaches compounds for use as inhibitors of acyl coenzyme A:cholesterol acyltransferase of a generic structure and specifically the following compound:

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RN 134989-87-0 CA
 CN Urea, N-heptyl-N'-5-isoquinoliny-1-yl-N-[[4-(3-methylbutyl)phenyl]methyl]-
 (9CI) (CA INDEX NAME)

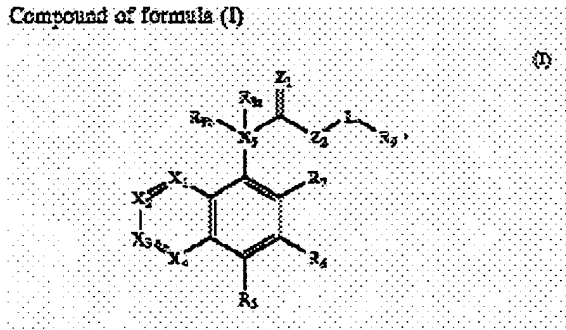


8. Claims 1-37, 55-84, 93, 94, 107, 108, 114 and 115 are rejected under 35

U.S.C. 102(e) as being anticipated by Lee (US 2003/0158198 A1). Lee teaches

compounds of formula (I)

Compound of formula (I)



as inhibitors of vanilloid receptor subtype 1. These compounds encompass the instantly claimed compounds.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

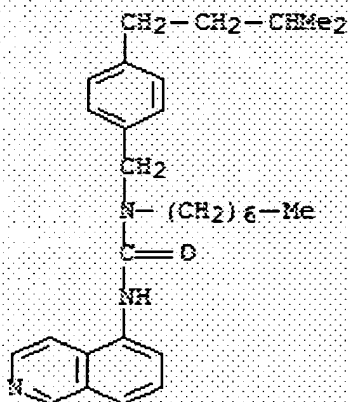
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-37, 55-84, 93, 94, 107, 108, 114 and 115 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 418071, further in view of Chang (US Patent #5,656,634).

EP teaches generically compounds of formula I and specifically

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RN 134989-87-0 CA
 CN Urea, N-heptyl-N'-5-isoquinolinylnyl-N-[[4-(3-methylbutyl)phenyl]methyl]-
 (9CI) (CA INDEX NAME)



The difference between the above compound and the instantly claimed compounds is that the instantly claimed compounds are in a generic scope with the availability of different substituents.


Chang teaches further compounds within a Markush similar to the EP having the same utility as inhibitors of acyl coenzyme a:cholesterol acyl transferase.

It would have been obvious to one of ordinary skill in the art to further substitute the above shown compound in accordance with the teachings of the EP with the reasonable expectation of getting compounds having utility as inhibitors of acyl coenzyme A: cholesterol acyltransferase. Rationale: The EP teaches a Markush of compounds with the above compound being specifically made with the teaching that the compounds that fit within the taught Markush have pharmaceutical activity.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. Margaret Seaman
Primary Examiner
Art Unit 1625

dms